PATENT COOPERATION TREATY

M.H

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 13 January 2000 (13.01.00)	
International application No. PCT/EP99/03822	**Applicant's or agent's file reference** FB/BM45324
International filing date (day/month/year) 31 May 1999 (31.05.99)	**Priority date** (day/month/year) 03 June 1998 (03.06.98)
Applicant VINALS-BASSOLS, Carlota	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

06 December 1999 (06.12.99)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

A. Karkachi

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

TYRRELL, Arthur W.R.
SMITHKLINE BEECHAM
Corporate Intellectual Property
Two New Horizons Court
Brentford
Middlesex TW8 9EP
GRANDE BRETAGNE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	19.09.00
Applicant's or agent's file reference FB/sh/bm45324	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP99/03822	31/05/1999	03/06/1998

Applicant
SMITHKLINE BEECHAM BIOLOGICALS S.A. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Vullo, C Tel.+49 89 2399-8061

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
FB/sh/bm45324		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP99/03822	31/05/1999	03/06/1998
International Patent Classification (IPC) or national classification and IPC C12N15/31		
Applicant SMITHKLINE BEECHAM BIOLOGICALS S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
06/12/1999	19.03.00
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Ury, A Telephone No. +49 89 2399 8411

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP99/03822

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-66	as originally filed				

Claims, No.:

1-26	as received on	01/08/2000	with letter of	31/07/2000	

Drawings, sheets:

1/26-26/26	as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-14, 16-21, 23-26
	No:	Claims	15, 22
Inventive step (IS)	Yes:	Claims	1-14, 16-21, 23-26
	No:	Claims	15, 22
Industrial applicability (IA)	Yes:	Claims	1-26
	No:	Claims	

2. Citations and explanations

see separate sheet

Item V.

I) The BASB027 gene of SEQ ID NO:1 derives from genomic DNA sequences of the *Moraxella catarrhalis* strain ATCC 43617 (see Example 1, page 49 of the application). Since no technical feature distinguishes a "live microorganism comprising an isolated recombinant polynucleotide according to any one of claims 7-14" from the above mentioned naturally occurring strain, the subject-matter of present claim 15 lacks novelty under Article 33.2 PCT.

II) A polypeptide **comprising** (see claims 1-3 and 6) an amino acid sequence according to the invention is a polypeptide which can also comprise **any other known sequence** (fusion proteins etc...; see claim 6).
An antibody immunospecific for such a polypeptide (see claim 22) can be any known antibody immunospecific for said other known sequence. Thus, claim 22 covers known antibodies and therefore lacks novelty under Article 33.2 PCT.

III) The present application is based on the provision of nucleic acids (two variants) encoding the BASB027 polypeptides (two variants) from Moraxella catarrhalis.
The claimed polypeptides and polynucleotides are neither disclosed nor rendered obvious by the prior art cited in the international search report.
Thus, the claims not objected to for lack of novelty fulfil the requirements of Article 33.2 and 3 PCT.

BM45324

CLAIMS:

1. An isolated polypeptide comprising an amino acid sequence which has at least 85% identity to the amino acid sequence selected from the group consisting of: SEQ ID NO:2 and SEQ ID NO:4, over the entire length of SEQ ID NO:2 or SEQ ID NO:4 respectively.

2. An isolated polypeptide as claimed in claim 1 in which the amino acid sequence has at least 95% identity to the amino acid sequence selected from the group consisting of: SEQ ID NO:2 and SEQ ID NO:4, over the entire length of SEQ ID NO:2 or SEQ ID NO:4 respectively.

3. The polypeptide as claimed in claim 1 comprising the amino acid sequence selected from the group consisting of: SEQ ID NO:2 and SEQ ID NO:4.

4. An isolated polypeptide having the amino acid sequence selected from the group consisting of SEQ ID NO:2 or SEQ ID NO:4.

5. An immunogenic fragment of the polypeptide as claimed in any one of claims 1 to 4 in which the immunogenic fragment is capable of raising an immune response (if necessary when coupled to a carrier) which recognises the polypeptide of SEQ ID NO:2 or SEQ ID NO:4.

6. A polypeptide as claimed in any of claims 1 to 5 wherein said polypeptide is part of a larger fusion protein.

7. An isolated polynucleotide encoding a polypeptide as claimed in any of claims 1 to 6.

8. An isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide that has at least 85% identity to the amino acid sequence of SEQ ID NO:2 or 4 over the entire length of SEQ ID NO:2 or 4 respectively; or a nucleotide sequence complementary to said isolated polynucleotide.

9. An isolated polynucleotide comprising a nucleotide sequence that has at least 85% identity to a nucleotide sequence encoding a polypeptide of SEQ ID NO:2 or 4 over the entire coding region; or a nucleotide sequence complementary to said isolated polynucleotide.

10. An isolated polynucleotide which comprises a nucleotide sequence which has at least 85% identity to that of SEQ ID NO:1 or 3 over the entire length of SEQ ID NO:1 or 3 respectively; or a nucleotide sequence complementary to said isolated polynucleotide.

11. The isolated polynucleotide as claimed in any one of claims 7 to 10 in which the identity is at least 95% to SEQ ID NO:1 or 3.

12. An isolated polynucleotide comprising a nucleotide sequence encoding the polypeptide of SEQ ID NO:2 or SEQ ID NO:4.

13. An isolated polynucleotide comprising the polynucleotide of SEQ ID NO:1 or SEQ ID NO:3.

14. An isolated polynucleotide comprising a nucleotide sequence encoding the polypeptide of SEQ ID NO:2, SEQ ID NO:4 obtainable by screening an appropriate library under stringent hybridization conditions with a labeled probe having the sequence of SEQ ID NO:1 or SEQ ID NO:3 or a fragment thereof.

15. An expression vector or a live microorganism comprising an isolated recombinant polynucleotide according to any one of claims 7 - 14.

16. A host cell comprising the expression vector of claim 15 expressing an isolated polypeptide comprising an amino acid sequence that has at least 85% identity to the amino acid sequence selected from the group consisting of: SEQ ID NO:2 and SEQ ID NO:4, or a membrane of the host cell comprising the expressed polypeptide.

17. A process for producing a polypeptide of claims 1 to 6 comprising culturing a host cell of claim 16 under conditions sufficient for the production of said polypeptide and recovering the polypeptide from the culture medium.

18. A process for expressing a polynucleotide of any one of claims 7 – 14 comprising transforming a host cell with the expression vector comprising at least one of said polynucleotides and culturing said host cell under conditions sufficient for expression of any one of said polynucleotides.

19. A vaccine composition comprising an effective amount of the polypeptide of any one of claims 1 to 6 and a pharmaceutically acceptable carrier.

20. A vaccine composition comprising an effective amount of the polynucleotide of any one of claims 7 to 14 and a pharmaceutically effective carrier.

21. The vaccine composition according to either one of claims 19 or 20 wherein said composition comprises at least one other *Neisseria meningitidis* antigen.

22. An antibody immunospecific for the polypeptide or immunological fragment as claimed in any one of claims 1 to 6.

23. A method of diagnosing a *Neisseria meningitidis* infection, comprising identifying a polypeptide as claimed in any one of claims 1 - 6, or an antibody that is immunospecific for said polypeptide, present within a biological sample from an animal suspected of having such an infection.

24. Use of a composition comprising an immunologically effective amount of a polypeptide as claimed in any one of claims 1 – 6 in the preparation of a medicament for use in generating an immune response in an animal.

25. Use of a composition comprising an immunologically effective amount of a polynucleotide as claimed in any one of claims 7 - 14 in the preparation of a medicament for use in generating an immune response in an animal.

26. A therapeutic composition useful in treating humans with *Neisseria meningitidis* comprising at least one antibody directed against the polypeptide of claims 1 – 6 and a suitable pharmaceutical carrier.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
FB/BM45324		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP 99/03822	31/05/1999	08/03/1998
Applicant		
SMITHKLINE BEECHAM BIOLOGICALS S.A. et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [X] contained in the international application in written form.

   [X] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [X] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [X] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [ ] the text is approved as submitted by the applicant.

   [X] the text has been established by this Authority to read as follows:

   BASB027 PROTEINS AND GENES FROM MORAXELLA CATARRHALIS, ANTIGENS, ANTIBODIES, AND USES

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 4

   [ ] as suggested by the applicant.

   [X] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 99/03822

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 C12N15/31 C12N15/62 C07K14/21 C07K16/12 A61K39/02
A61K39/40 G01N33/50

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 C12N C07K A61K G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DATABASE EMBL 'Online! ID NGU81959, AC U81959, 22 February 1997 (1997-02-22) MANNING D S ET AL.: "Neisseria gonorrhoeae outer membrane protein (omp85) gene, complete cds." XP002124670 Note: 32.4% aa sequence identity with SEQ ID NO:2 in 816 aa overlap. the whole document	1-16
T	-& MANNING D S ET AL.: "Omp85 proteins of Neisseria gonorrhoeae and Neisseria meningitidis are similar to Haemophilus influenzae D-15-Ag and Pasteurella multocida Oma87." MICROBIAL PATHOGENESIS, vol. 25, July 1998 (1998-07), pages 11-21, XP000857391 abstract	1-24

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 December 1999	11/01/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	van de Kamp, M

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
	page 16, line 4-9 figure 7A	
A	WO 94 12641 A (CONNAUGHT LAB ;CHONG PELE (CA); THOMAS WAYNE (AU); YANG YAN PING () 9 June 1994 (1994-06-09) Note: 31.0% aa sequence identity of sequence from Fig. 1A with SEQ ID NO:2 in 823 aa overlap. the whole document page 1	1-24
A	MURPHY T F: "Branhamella catarrhalis: epidemiology, surface antigenic structure, and immune response." MICROBIOL. REVIEWS, vol. 60, no. 2, June 1996 (1996-06), pages 267-279, XP002102898 cited in the application page 271, right-hand column, paragraph 5 -page 273, right-hand column, paragraph 3 table 3 page 274, right-hand column, paragraph 2 -page 275, right-hand column, paragraph 3	1-24
A	BARTOS L C ET AL: "Comparison of the outer membrane proteins of 50 strains of Branhamella catarrhalis." JOURNAL OF INFECTIOUS DISEASES, vol. 158, no. 4, October 1988 (1988-10), page 761-765 XP000562830 ISSN: 0022-1899 abstract figures 1,2 table 1	1-24
A	WO 97 32980 A (LOOSMORE SHEENA M ;SCHRYVERS ANTHONY B (CA); CONNAUGHT LAB (CA); Y) 12 September 1997 (1997-09-12) the whole document	1-24

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 99/03822

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9412641 A	09-06-1994	AU 683435 B	13-11-1997
		AU 5556594 A	22-06-1994
		BR 9307510 A	01-06-1999
		CA 2149319 A	09-06-1994
		EP 0668916 A	30-08-1995
		JP 2907552 B	21-06-1999
		JP 8502417 T	19-03-1996
WO 9732980 A	12-09-1997	AU 1865397 A	22-09-1997
		CA 2248095 A	12-09-1997
		CN 1217748 A	26-05-1999
		EP 0885300 A	23-12-1998
		NZ 331777 A	29-09-1999

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
FB/BM45324		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP 99/ 03822	31/05/1999	08/03/1998
Applicant		
SMITHKLINE BEECHAM BIOLOGICALS S.A. et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

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   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [X] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [X] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [ ] the text is approved as submitted by the applicant.

   [X] the text has been established by this Authority to read as follows:

   BASB027 PROTEINS AND GENES FROM MORAXELLA CATARRHALIS, ANTIGENS, ANTIBODIES, AND USES

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 4

   [ ] as suggested by the applicant.

   [X] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
	page 16, line 4-9 figure 7A	
A	WO 94 12641 A (CONNAUGHT LAB ;CHONG PELE (CA); THOMAS WAYNE (AU); YANG YAN PING () 9 June 1994 (1994-06-09) Note: 31.0% aa sequence identity of sequence from Fig. 1A with SEQ ID NO:2 in 823 aa overlap. the whole document page 1	1-24
A	MURPHY T F: "Branhamella catarrhalis: epidemiology, surface antigenic structure, and immune response." MICROBIOL. REVIEWS, vol. 60, no. 2, June 1996 (1996-06), pages 267-279, XP002102898 cited in the application page 271, right-hand column, paragraph 5 -page 273, right-hand column, paragraph 3 table 3 page 274, right-hand column, paragraph 2 -page 275, right-hand column, paragraph 3	1-24
A	BARTOS L C ET AL: "Comparison of the outer membrane proteins of 50 strains of Branhamella catarrhalis." JOURNAL OF INFECTIOUS DISEASES, vol. 158, no. 4, October 1988 (1988-10), page 761-765 XP000562830 ISSN: 0022-1899 abstract figures 1,2 table 1	1-24
A	WO 97 32980 A (LOOSMORE SHEENA M ;SCHRYVERS ANTHONY B (CA); CONNAUGHT LAB (CA); Y) 12 September 1997 (1997-09-12) the whole document	1-24

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 99/03822

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9412641 A	09-06-1994	AU 683435 B	13-11-1997
		AU 5556594 A	22-06-1994
		BR 9307510 A	01-06-1999
		CA 2149319 A	09-06-1994
		EP 0668916 A	30-08-1995
		JP 2907552 B	21-06-1999
		JP 8502417 T	19-03-1996
WO 9732980 A	12-09-1997	AU 1865397 A	22-09-1997
		CA 2248095 A	12-09-1997
		CN 1217748 A	26-05-1999
		EP 0885300 A	23-12-1998
		NZ 331777 A	29-09-1999

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 99/03822

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 C12N15/31 C12N15/62 C07K14/21 C07K16/12 A61K39/02
A61K39/40 G01N33/50

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 C12N C07K A61K G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DATABASE EMBL 'Online! ID NGU81959, AC U81959, 22 February 1997 (1997-02-22) MANNING D S ET AL.: "Neisseria gonorrhoeae outer membrane protein (omp85) gene, complete cds." XP002124670 Note: 32.4% aa sequence identity with SEQ ID NO:2 in 816 aa overlap. the whole document	1-16
T	-& MANNING D S ET AL.: "Omp85 proteins of Neisseria gonorrhoeae and Neisseria meningitidis are similar to Haemophilus influenzae D-15-Ag and Pasteurella multocida Oma87." MICROBIAL PATHOGENESIS, vol. 25, July 1998 (1998-07), pages 11-21, XP000857391 abstract	1-24
	-/--	

[X] Further documents are listed in the continuation of box C.

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° Special categories of cited documents :

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"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 December 1999	11/01/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	van de Kamp, M

Form PCT/ISA/210 (second sheet) (July 1992)

CLAIMS:

1. An isolated polypeptide comprising an amino acid sequence which has at least 85% identity to the amino acid sequence selected from the group consisting of: SEQ ID NO:2, SEQ ID NO:4.

2. An isolated polypeptide as claimed in claim 1 in which the amino acid sequence has at least 95% identity to the amino acid sequence selected from the group consisting of: SEQ ID NO:2, SEQ ID NO:4.

3. The polypeptide as claimed in claim 1 comprising the amino acid sequence selected from the group consisting of: SEQ ID NO:2, SEQ ID NO:4.

4. An isolated polypeptide of SEQ ID NO:2 or SEQ ID NO:4.

5. An immunogenic fragment of the polypeptide as claimed in any one of claims 1 to 4 in which the immunogenic activity of said immunogenic fragment is substantially the same as the polypeptide of SEQ ID NO:2, SEQ ID NO:4.

6. An isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide that has at least 85% identity to the amino acid sequence of SEQ ID NO:2, 4 over the entire length of SEQ ID NO:2, 4 respectively; or a nucleotide sequence complementary to said isolated polynucleotide.

7. An isolated polynucleotide comprising a nucleotide sequence that has at least 85% identity to a nucleotide sequence encoding a polypeptide of SEQ ID NO:2, 4 over the entire coding region; or a nucleotide sequence complementary to said isolated polynucleotide.

8. An isolated polynucleotide which comprises a nucleotide sequence which has at least 85% identity to that of SEQ ID NO:1, 3 over the entire length of SEQ ID NO:1, 3 respectively; or a nucleotide sequence complementary to said isolated polynucleotide.

9. The isolated polynucleotide as claimed in any one of claims 6 to 8 in which the identity is at least 95% to SEQ ID NO:1, 3.

10. An isolated polynucleotide comprising a nucleotide sequence encoding the polypeptide of SEQ ID NO:2, SEQ ID NO:4.

11. An isolated polynucleotide comprising the polynucleotide of SEQ ID NO:1, SEQ ID NO:3.

12. An isolated polynucleotide comprising a nucleotide sequence encoding the polypeptide of SEQ ID NO:2, SEQ ID NO:4 obtainable by screening an appropriate library under stringent hybridization conditions with a labeled probe having the sequence of SEQ ID NO:1, SEQ ID NO:3 or a fragment thereof.

13. An expression vector or a recombinant live microorganism comprising an isolated polynucleotide according to any one of claims 6 - 12.

14. A host cell comprising the expression vector of claim 13 or a subcellular fraction or a membrane of said host cell expressing an isolated polypeptide comprising an amino acid sequence that has at least 85% identity to the amino acid sequence selected from the group consisting of: SEQ ID NO:2, SEQ ID NO:4.

15. A process for producing a polypeptide comprising an amino acid sequence that has at least 85% identity to the amino acid sequence selected from the group consisting of: SEQ ID NO:2, SEQ ID NO:4 comprising culturing a host cell of claim 14 under conditions

sufficient for the production of said polypeptide and recovering the polypeptide from the culture medium.

16. A process for expressing a polynucleotide of any one of claims 6 – 12 comprising transforming a host cell with the expression vector comprising at least one of said polynucleotides and culturing said host cell under conditions sufficient for expression of any one of said polynucleotides.

17. A vaccine composition comprising an effective amount of the polypeptide of any one of claims 1 to 5 and a pharmaceutically acceptable carrier.

18. A vaccine composition comprising an effective amount of the polynucleotide of any one of claims 6 to 12 and a pharmaceutically effective carrier.

19. The vaccine composition according to either one of claims 17 or 18 wherein said composition comprises at least one other *Moraxella catarrhalis* antigen.

20. An antibody immunospecific for the polypeptide or immunological fragment as claimed in any one of claims 1 to 5.

21. A method of diagnosing a *Moraxella catarrhalis* infection, comprising identifying a polypeptide as claimed in any one of claims 1 - 5, or an antibody that is immunospecific for said polypeptide, present within a biological sample from an animal suspected of having such an infection.

22. Use of a composition comprising an immunologically effective amount of a polypeptide as claimed in any one of claims 1 – 5 in the preparation of a medicament for use in generating an immune response in an animal.

23. Use of a composition comprising an immunologically effective amount of a polynucleotide as claimed in any one of claims 6 - 12 in the preparation of a medicament for use in generating an immune response in an animal.

24. A therapeutic composition useful in treating humans with *Moraxella catarrhalis* disease comprising at least one antibody directed against the polypeptide of claims 1 – 5 and a suitable pharmaceutical carrier.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

15

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
FB/sh/bm45324		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP99/03822	31/05/1999	03/06/1998
International Patent Classification (IPC) or national classification and IPC C12N15/31		
Applicant SMITHKLINE BEECHAM BIOLOGICALS S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
06/12/1999	19.09.00
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Ury, A Telephone No. +49 89 2399 8411

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP99/03822

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-66	as originally filed				

Claims, No.:

1-26	as received on	01/08/2000	with letter of	31/07/2000	

Drawings, sheets:

1/26-26/26	as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-14, 16-21, 23-26
	No:	Claims	15, 22
Inventive step (IS)	Yes:	Claims	1-14, 16-21, 23-26
	No:	Claims	15, 22
Industrial applicability (IA)	Yes:	Claims	1-26
	No:	Claims	

2. Citations and explanations

see separate sheet

Item V.

I) The BASB027 gene of SEQ ID NO:1 derives from genomic DNA sequences of the *Moraxella catarrhalis* strain ATCC 43617 (see Example 1, page 49 of the application). Since no technical feature distinguishes a "live microorganism comprising an isolated recombinant polynucleotide according to any one of claims 7-14" from the above mentioned naturally occurring strain, the subject-matter of present claim 15 lacks novelty under Article 33.2 PCT.

II) A polypeptide **comprising** (see claims 1-3 and 6) an amino acid sequence according to the invention is a polypeptide which can also comprise **any other known sequence** (fusion proteins etc...; see claim 6).
An antibody immunospecific for such a polypeptide (see claim 22) can be any known antibody immunospecific for said other known sequence. Thus, claim 22 covers known antibodies and therefore lacks novelty under Article 33.2 PCT.

III) The present application is based on the provision of nucleic acids (two variants) encoding the BASB027 polypeptides (two variants) from Moraxella catarrhalis.
The claimed polypeptides and polynucleotides are neither disclosed nor rendered obvious by the prior art cited in the international search report.
Thus, the claims not objected to for lack of novelty fulfil the requirements of Article 33.2 and 3 PCT.